

# PSJ3

## Exhibit 563

Message

**From:** Mays, Steve [SMays@amerisourcebergen.com]  
**Sent:** 6/25/2013 6:45:02 PM  
**To:** Ducca, Anita [aducca@hdmanet.org]; Giacalone, Robert [/O=CAH/OU=Cardinal Health/cn=Recipients/cn=Robert.Giacalone]  
**CC:** Reardon, Steve [/O=CAH/OU=Cardinal Health/cn=Recipients/cn=Steve.Reardon]  
**Subject:** RE: HDMA Review Requested -- by Tuesday, June 25 COB

Anita,

The only issue we have regards sharing a customer's thresholds with them. I'm ok with all of Bob's other Edits. We have a situation currently where certain HDMA members provide this information to their customers and others do not. DEA has been asked this before and we didn't get an answer.

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**From:** Ducca, Anita [mailto:aducca@hdmanet.org]  
**Sent:** Tuesday, June 25, 2013 2:26 PM  
**To:** Mays, Steve; Giacalone, Robert  
**Cc:** Reardon, Steve  
**Subject:** RE: HDMA Review Requested -- by Tuesday, June 25 COB

Steve and Bob, your reviews and suggestions are terrific. They really help this out.

I'd like to make a couple of comments on thresholds. First, if you recall, during our review conference call, we discussed asking DEA whether it was ok to tell customers their thresholds, would be acceptable "ratios" for purchases of controlled substances vs. non-controls, and similar questions.

The idea was to try to get DEA to give specifics on acceptable amounts, etc. However, the RAC felt we'd never get answers from DEA if we asked them these types of questions directly. So we decided to ask about "trends" instead. So, that's the way we wrote up question 9, which among other things asks for "trends" in "...total volumes of products being sold/shipped per distributor customer..." as more likely to elicit a response.

Also, way back even before this all got rolling in 2007, when DEA was first bringing out their distributor program, I remember a DEA-provided one-page cursory guidance on SO's. Unfortunately, I haven't been able to get my hands on that document, but I distinctly remember that it had a DEA suggested numerical volume limit (I believe for retail pharmacy) which RAC members felt was very low.

Thus, if we do by some chance get an answer from DEA on a threshold now, we risk having DEA make it very low.

So I'll ask Steve M: Do you still prefer to ask the question as the attorneys gave it to you or would the HDMA draft #9 (or Bob G's version) be acceptable? I'm fine with putting the question in as you have it from your colleagues, but it should

go back out to the RAC for follow-up review/discussion since it's different from the consensus reached on the phone call.

To make it easier, #9 (including Bob G's recent edits) is cut and pasted below.

9. HDMA requests that DEA provide current trend information? For example, we're interested in such trends as:
- The comparative amounts and/or percentages of controlled substances being ordered, (or shipped or dispensed) compared to non-controlled substances? A breakdown by such factors as geographical location (particularly Florida) or by the purchaser's class of trade e.g., retail pharmacy vs. hospitals vs. pain clinic, or specific drug product such as oxycodone, hydrocodone, etc. would also be helpful.
  - The total volumes of products being sold/shipped per distributor customer by the same factors, e.g., geographical location, class of trade, specific drug product?
  - The specific Rx drugs (or combinations of drugs or changes in combinations) that are being abused that distributors should be aware of?
  - Are there factors that are affecting the trends that wholesale distributors should be aware of as they evaluate customers and their orders?

Any thoughts?

Anita

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**From:** Mays, Steve [<mailto:SMays@amerisourcebergen.com>]  
**Sent:** Tuesday, June 25, 2013 12:08 PM  
**To:** Giacalone, Robert; Ducca, Anita  
**Cc:** Reardon, Steve  
**Subject:** RE: HDMA Review Requested -- by Tuesday, June 25 COB

Per our conversation, let's keep the threshold question in for now unless the other member s object to asking.

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**From:** Giacalone, Robert [<mailto:Robert.Giacalone@cardinalhealth.com>]  
**Sent:** Tuesday, June 25, 2013 11:55 AM  
**To:** Mays, Steve; Anita Ducca  
**Cc:** Reardon, Steve  
**Subject:** RE: HDMA Review Requested -- by Tuesday, June 25 COB

Anita (and Steve),

Will defer to Steve as to what questions he believes should be included in the request. Thanks, Bob.

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**From:** Mays, Steve [<mailto:SMays@amerisourcebergen.com>]  
**Sent:** Tuesday, June 25, 2013 10:29 AM  
**To:** Giacalone, Robert; Anita Ducca  
**Cc:** Reardon, Steve  
**Subject:** FW: HDMA Review Requested -- by Tuesday, June 25 COB

Maybe we need to discuss. My legal team seems to feel strongly about the first question because we are currently at a competitive disadvantage without the answer.

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**From:** Campbell, Elizabeth  
**Sent:** Tuesday, June 25, 2013 10:18 AM  
**To:** Mays, Steve; Casalenuovo, Christopher J.  
**Subject:** RE: HDMA Review Requested -- by Tuesday, June 25 COB

Steve,

His proposed question is a different question altogether and I definitely do not want to ask if the DEA wants us to educate our customers on diversion. They – of course – will say yes. I don't want to put any additional, vague requirements on us. I still think we should ask the threshold question as Chris originally phrased it. It's a yes or no question and the answer is important to us. I'm good with the other questions.

Thanks!

Elizabeth

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**From:** Mays, Steve  
**Sent:** Tuesday, June 25, 2013 9:32 AM  
**To:** Casalenuovo, Christopher J.; Campbell, Elizabeth  
**Subject:** FW: HDMA Review Requested -- by Tuesday, June 25 COB

Chris,  
I submitted to HDMA and the CAH attorney that I have been working with. I'm ok with his responses below if you are. Let me know if you have any concerns with this approach. He makes some good points.

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**From:** Giacalone, Robert [<mailto:Robert.Giacalone@cardinalhealth.com>]  
**Sent:** Tuesday, June 25, 2013 8:41 AM  
**To:** Mays, Steve; Anita Ducca  
**Cc:** Reardon, Steve  
**Subject:** RE: HDMA Review Requested -- by Tuesday, June 25 COB

Steve (and Anita):

I think they are good questions to ask, but would recommend they be modified. Please see my comments/proposed questions below. Thanks, Bob.

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**From:** Mays, Steve [<mailto:SMays@amerisourcebergen.com>]  
**Sent:** Monday, June 24, 2013 8:28 PM  
**To:** Giacalone, Robert; Anita Ducca  
**Subject:** Fwd: HDMA Review Requested -- by Tuesday, June 25 COB

Here are a few suggested questions for your consideration:

1. Can/should we tell customers their thresholds?

Comment: Would definitely be nice to know, but doubt we'll get any answer. I believe one or more of us may have asked some variation of that question before of DEA and have got no response to date. In addition, if DEA says "no" what exactly does that mean? We can provide no guidance at all to customers? Again, not sure what this gets us other than, at best, an ambiguous response lacking the clarity and consistency we would want. Perhaps an alternative question offered. Proposed question: What is DEA's position on wholesalers working with customers to educate them on potential signs of diversion? Should wholesalers share information with pharmacies to help them understand what actions on the pharmacy's part might constitute potential diversion in the eyes of a third party such as a wholesaler? If so, does DEA have any recommendations as to what information wholesalers should share with pharmacies they service to help educate them so as to prevent diversion?"

2. Would the DEA like to review our thresholds to determine if they are acceptable? Better yet, would the DEA like to provide us with thresholds that we can use?

Comment: We know that DEA will not provide guidance on threshold determinations or sign-off on SOM systems. They have made this clear repeatedly, so I'm not sure asking the first question gets us anywhere and may irritate them. Perhaps the second question could be modified. Proposed question: "Would the DEA be able to provide us with suggested "model" thresholds for different customer classes that can be used as a basis for a wholesaler to set its own thresholds? For example, are there recommended thresholds that ideally should be acceptable or expected for products such as oxycodone and hydrocodone when you have small, medium or large retail independent pharmacies. How do those numbers compare to pharmacies that service hospice centers? Long term care facilities? Adjacent to hospital emergency rooms? Etc."

3. Are there other objective criteria/guidelines that the DEA can offer that we take into account? For example, if a customer's controlled substance purchases are X% of its overall purchases, we should cut off that customer.

Comment: This question is good, but would recommend modifying the example following since it may be to black and white to elicit an answer or we get an answer that's relatively worthless (such as a pharmacy that only purchase oxycodone 30mg and no other legend drugs should be scrutinized). Proposed question: "Are there other objective criteria/guidelines that the DEA can offer that we take into account when evaluating potential or existing customers? For example, if a customer's controlled substance purchases are X% of its overall purchases, are there other specific criteria or factors that a wholesaler should consider when evaluating that customer. If so, what are they?"

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**From:** Mays, Steve

**Sent:** Monday, June 24, 2013 10:24 AM


**To:** Campbell, Elizabeth; Casalenuovo, Christopher J.

**Subject:** FW: HDMA Review Requested -- by Tuesday, June 25 COB

FYI

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**From:** Giacalone, Robert [<mailto:Robert.Giacalone@cardinalhealth.com>]

**Sent:** Monday, June 24, 2013 8:19 AM

**To:** Mays, Steve; Ducca, Anita

**Cc:** Reardon, Steve

**Subject:** RE: HDMA Review Requested -- by Tuesday, June 25 COB



Agree with Steve's edits. Made a couple more (in green highlight) in the attached redlined version with comments. Should be good to go. Thanks, Bob.

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**From:** Mays, Steve [<mailto:SMays@amerisourcebergen.com>]  
**Sent:** Sunday, June 23, 2013 3:31 PM  
**To:** Giacalone, Robert; Ducca, Anita  
**Cc:** Reardon, Steve  
**Subject:** FW: HDMA Review Requested -- by Tuesday, June 25 COB

Bob,  
Thanks for all the effort you put into your review and edits. You just saved me a ton of time. I have added just a few minor changes and added a few comments of my own.

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**From:** Giacalone, Robert [<mailto:Robert.Giacalone@cardinalhealth.com>]  
**Sent:** Sunday, June 23, 2013 2:34 PM  
**To:** Ducca, Anita  
**Cc:** Mays, Steve; Reardon, Steve  
**Subject:** RE: HDMA Review Requested -- by Tuesday, June 25 COB

Anita (and Steve):

Please see attached suggested edits and comments to the draft questions. In order to expedite the process, I have cc-ed Steve Mays in order to avoid duplicating efforts. As mentioned I have also deleted references to the ICG based upon the RAC discussion which took place. Please let me know if you have any questions.

Thanks, Bob.

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**From:** Ducca, Anita [<mailto:aducca@hdmanet.org>]  
**Sent:** Friday, June 21, 2013 2:15 PM  
**To:** Ducca, Anita  
**Subject:** HDMA Review Requested -- by Tuesday, June 25 COB

**To: Regulatory Affairs Committee**

Per yesterday's discussion, this is a reminder to please e-mail your review/edits to the DEA questions to me **by Tuesday, June 25 COB**. For your convenience, I've attached the latest version, which was also sent in Allison Tuszynski's e-mail of last week. (Kindly do not circulate these questions outside of your company's offices as they're still in draft.)

We'll revise them according to your changes and send them to DEA as soon as possible. However, if we see any major discrepancies among your responses, we'll make a judgment call as to whether we need an additional teleconference to resolve them.

If you have any questions, please feel free to contact me.

Have a wonderful weekend!

*Anita*

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